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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,265

08/02/2005

Joachim Moormann

RO4082US (#90568)

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28672 7590 03/27/2008
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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,265	Applicant(s) MOORMANN ET AL.	
	Examiner Erich A. Leeseer	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-52 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-30 have been canceled. Newly added claims 31-52 are currently pending and under examination.

Claim Rejections - 35 USC § 101

Examiner rejection of claims 22 and 30 under 35 U.S.C. 101 is rendered moot in view of Applicant's cancellation of these claims.

Claim Rejections 35 U.S.C. § 112

Examiner withdraws his previous rejection of claims 1, 9, 18, 22, and 30 under 35 U.S.C. 112, second paragraph, because Applicant's amendment of these claims obviates the rejection.

Claim Rejections 35 U.S.C. § 103

Examiner maintains his previous rejection of claims 1-5 and 23-24 (now claims 31-33) and expands the rejection to added claim 34-52 under 35 U.S.C. § 103(a) as being unpatentable over Yadav, et al., *Microwave-assisted Rapid Synthesis of the Cytotoxic Alkaloid Luotonin A*, Tetrahedron Letters, Vol. 43, 1905-07 (2002) for the reasons of record in the Office Action dated August 23, 2007.

Instant claim 31 is drawn to a process for producing pegenone by converting 1 mole of isatoic anhydride with 1.5 to 5 moles of 2-pyrrolidone to form a reaction mixture; heating the reaction mixture to an initial temperature of 70-130 °C; maintaining this initial temperature from 0.5 to 2 hours; subsequently heating the reaction mixture to a subsequent temperature of 140-200

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°C; maintaining this subsequent temperature from 1 to 8 hours; and crystallizing the reaction product pegenone to isolate it from the reaction mixture. Instant claims 32-33 further limit the molar ratio of the reactants; instant claims 34-35 and 37-39 further limit the temperature steps; instant claim 40 sets forth a process for making a similar product with similar steps; and instant claims 36 and 41-52 sets forth an additional steps in making the product.

Yadav, et al. teaches making peganone by mixing equal molar ratios of isatoic anhydride and 2-pyrrolidone. Note reactant 1e and product 4e in scheme 2 on page 1906, which only differ from the instant process in having equal molar ratios of isatoic anhydride and 2-pyrrolidone whereas the instant process demands that “2-pyrrolidone in an amount of 1.5 to 5 mol relative to the amount of compound (II).” See claim 31. In addition, Yadav utilizes only one heating step at a temperature of 120 °C from 5 to 8 hours, though this temperature falls within the initial temperature range of instant claim 31 and heating period falls within the range of the subsequent heating period of instant claim 31.

Although Yadav, et al. does not provide an explicit motivation for a skilled artisan in this field to modify the molar ratios of the two reactants relative to one another, the instant process would have been obvious because “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. --, 82 USPQ2d 1385 (2007). It would have been obvious to one having ordinary skill in the art at the time that the invention was made to increase the reactants and expect such addition to drive the chemical reaction to the right and thereby increase products.

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See specification page 5. Therefore, Examiner has made a finding that one of ordinary skill in the art could have pursued the known potential options with a reasonable expectation of success.

As such, it is Examiner's position that changing the molar ratio of the reactants of Yadav, et al. is an obvious modification of Yadav, et al. to one skilled in the art.

Although Applicant apparently is aware of Examiner's position: "Yadav, et al. teach the limitations of the present invention but do not teach a motivation for a skilled pharmaceutical chemist to modify the molar ratios of the two reactants relative to one another"; but, Applicant failed to address this position directly. Instead, Applicant argues that by incorporating a further limitation from former claim 6 into the broadest claim, said limitation distinguishes the instant invention over the prior art. Despite finding that former claim 6 was allowable over Yadav, upon further review Examiner does not find that heating the reaction mixture to two separate temperatures for two separate periods of time is a critical limitation of the present invention over the prior art. Therefore, Applicant's slight modification of Yadav's process does not optimize the production method and thus does not seem to impart patentability because the temperature modifications are within the purview of the skilled artisan. Criticality of the two different temperature ranges using temperatures which overlap with the overall reaction temperatures disclosed in the prior art are obvious variations absent some clearly articulated unexpected result(s) supported by evidence on the record.

As such, it is Examiner's position that maintaining an initial temperature for a period of time before maintaining a second temperature for a second period of time is not a significant enough of a modification over the prior art to impart patentability.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

**/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624**

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Patent Examiner, Art Unit 1624

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